Quoin Pharmaceuticals Announces Submission to Japanese MHLW for Orphan Drug Designation for QRX003 in Netherton Syndrome

January 27, 2026

Confirmation Received from MHLW That QRX003 Qualifies for Both Orphan Drug Designation and Fast Track Regulatory Review Status

Quoin Initiating the Establishment of a Japanese Subsidiary to Facilitate Self-Commercialization of QRX003 in Japan, if Approved

Orphan Drug Designation Previously Granted by Both the U.S. Food and Drug Administration (FDA) and the European Medicines (EMA) Agency in 2025

ASHBURN, Va., Jan. 27, 2026 (GLOBE NEWSWIRE) -- Quoin Pharmaceuticals Ltd. (NASDAQ: QNRX) ("Quoin" or the "Company"), a late clinical-stage specialty pharmaceutical company focused on rare and orphan diseases, today announced that following a successful meeting with the Japanese MHLW that it has submitted an application for Orphan Drug Designation (ODD) for its lead product candidate, QRX003, for the treatment of Netherton Syndrome. At the meeting, the MHLW confirmed that QRX003 qualifies for both ODD and Fast Track regulatory review in Japan. If granted, QRX003 will have ODD status in Quoin's three core commercial territories of the US, EU and Japan.

The MHLW's Orphan Drug Designation program provides orphan status to therapies intended for the treatment, diagnosis, or prevention of rare diseases that affect fewer than 50,000 people in Japan. This designation provides certain benefits, including R&D subsidies, tax credits for qualified clinical testing, reduction of MHLW application fees, priority review and ten years of market exclusivity, if approved. QRX003 is on track to potentially become the first approved treatment for Netherton Syndrome.

"Following a successful meeting with MHLW, we are optimistic that QRX003 will be granted ODD status in Japan. We are also pleased to learn that MHLW has confirmed QRX003 will also qualify for Fast Track regulatory review status in Japan," said Dr. Michael Myers, CEO of Quoin Pharmaceuticals. "We are moving forward with our plans to establish our own commercial infrastructure in Japan, which is one of three core territories for QRX003 and our other pipeline products. Quoin remains steadfastly committed to completing the clinical development of QRX003 with a high degree of urgency on behalf of patients and families living with this devastating disease."

QRX003 lotion (4%) is being evaluated in two late-stage whole body pivotal clinical trials for Netherton Syndrome. Enrollment in both pivotal studies is expected to be completed in 1H 2026, top-line data is anticipated in the second half of 2026, and NDA submission is planned later in the year or early 2027. In 2025, QRX003 was granted Orphan Drug Designation for the treatment of Netherton Syndrome by both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

About Quoin Pharmaceuticals Ltd.

Quoin Pharmaceuticals Ltd. is a late clinical-stage specialty pharmaceutical company focused on developing and commercializing therapeutic products that treat rare and orphan diseases. We are committed to addressing unmet medical needs for patients, their families, communities and care teams. Quoin's innovative pipeline comprises several products in development that collectively have the potential to target a broad number of rare and orphan indications, including Netherton Syndrome, Peeling Skin Syndrome, Palmoplantar Keratoderma, Scleroderma, Microcystic Lymphatic Malformations, Venous Malformations, Angiofibroma and others. For more information, visit: www.quoinpharma.com or LinkedIn for updates.

Cautionary Note Regarding Forward Looking Statements

The Company cautions that statements in this press release that are not a description of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of words referencing future events or circumstances such as "expect," "intend," "plan," "anticipate," "believe," "look forward to," and "will," among others. All statements that reflect the Company's expectations, assumptions, projections, beliefs, or opinions about the future, other than statements of historical fact, are forward-looking statements, including, without limitation, statements relating to: establishing a subsidiary in Japan to facilitate self-commercialization of QRX003 if approved, the ODD application for QRX003 submitted in Japan for the treatment of Netherton Syndrome, the benefits of receiving orphan status under the MHLW's Orphan Drug Designation program, QRX003 being on track to become the first approved treatment for Netherton Syndrome, QRX003 being granted ODD status in Japan, QRX003 qualifying for Fast track regulatory review status in Japan, moving forward with plans to establish Quoin's own commercial infrastructure in Japan, completing the clinical development of QRX003 with a high degree of urgency on behalf of patients and families living with the disease, enrollment in two late-stage whole body pivotal clinical trials of QRX003 lotion (4%) for Netherton Syndrome being completed in 1H 2026, top-line data being anticipated in the second half of 2026, NDA submission being planned later in the year or early 2027, and Quoin's products in development collectively having the potential to target a broad number of rare and orphan indications, including Netherton Syndrome, Peeling Skin Syndrome, Palmoplantar Keratoderma, Scleroderma, Microcystic Lymphatic Malformations, Venous Malformations, Angiofibroma and others. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon the Company's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties including, but not limited to, the Company's ability to pursue its regulatory strategy; the Company's ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements; the Company's ability to complete clinical trials on time and achieve desired results and benefits as expected; and other factors discussed in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 and in other filings the

Company has made and may make with the SEC in the future. One should not place undue reliance on these forward-looking statements, which speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as may be required by law.

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